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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/998,975 | 11/19/2001 | Raymond Antoine Stokbroekx | JAB-1669 | 7975 |

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| EXAMINER |
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TRUONG, TAMTHOM NGO

| ART UNIT | PAPER NUMBER |
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1624

DATE MAILED: 05/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-------------------------------|-------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/998,975 | STOKBROEKX ET AL. |
| | Examiner Tamthom N. Truong | Art Unit 1624 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on ____.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-6 and 10-20 is/are pending in the application.

4a) Of the above claim(s) ____ is/are withdrawn from consideration.

5) Claim(s) ____ is/are allowed.

6) Claim(s) 1-4, 6, 13-16, and 18-20 is/are rejected.

7) Claim(s) 5,11 and 17 is/are objected to.

8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. ____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Applicant's preliminary amendment of 11-19-01 has been entered. Accordingly, claims 7-9 are now cancelled. Thus, only claims 1-6, and 10-12 remain for consideration along with new claims 13-20.

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-6, and 10-20 (part of each), drawn to compounds of formula (I), their composition, preparation, and method of treating angiogenesis using said compounds with X as nitrogen, classified in class 544, subclasses 333, 360, 364, 372.
 - II. Claims 1, 6, and 10-13 (part of each), drawn to compounds of formula (I), their composition, preparation, and method of treating angiogenesis using said compounds with X as -CH, classified in class 546, subclasses 208, 209, 210.

The inventions of groups I and II differ from each other because each group is drawn to a sequence of rings that is distinct and patentable over each other. Essentially, these are two independent inventions as compounds of one group can be utilized alone, and not in combination of those in other groups. Note, with a variable core as such, the common property is not enough to keep two groups in the same Markush claim. Furthermore, a prior art that renders obvious one invention would not do so to the other. Thus, restriction for examination purpose as indicated is proper. However, should applicant traverse on the ground that the two groups are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the

two groups to be obvious variant or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the invention unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. During a telephone conversation with Ms. Ellen C. Coletti on 5-16-02 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-6, and 10-20 (part of each). Affirmation of this election must be made by applicant in replying to this Office action.
3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 10 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a. Claim 10 recites the phrase, "...compounds of formula (I) are converted into each other...", is indefinite because it is unclear which compound gets converted to which.
- b. Claims 10 and 12 recite the limitation of "following art-known transformation reactions...", which is indefinite because one cannot ascertain what sequential steps are claimed. In a way, said limitation renders the two as *omnibus*-type claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. **Scope of Enablement:** Claims 1-4, 6, 13-16, and 18-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of formula (I) compounds with ring "A" as thiadiazolyl, phenyl, and pyridyl ring, does not reasonably provide enablement for the use of formula (I) compounds with ring "A" as other rings. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The following factors have been considered in the determination of an enabling disclosure:

- (1) The quantity of experimentation necessary;
- (2) The amount of direction or guidance presented;
- (3) The state of the prior art;
- (4) The relative skill of those in the art;

- (5) The predictability or unpredictability of the art;
- (6) The breadth of the claims;

[See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Int., 1986); also *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)].

The claims call for a plethora of compounds. However, in the specification, only compounds #1, 2, and 6 were tested for angiogenesis inhibitory activity. The result of three compounds does not provide sufficient evidence to conclude that all compounds of formula I would share the same property. Furthermore, no reference is found teaching a similar genus for inhibiting angiogenesis. Regarding enablement for chemical cases, the M.P.E.P. explicitly states that:

...in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. *In re Soll*, 97 F. 2d 623, 624, 38 USPQ 189, 191 (CCPA 1938). In cases involving unpredictable factors, such as most **chemical reactions** and **physiological activity**, more may be required. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970)...See also *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ 2d 1510, 1513 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 496, 20 USPQ 2d 1438, 1445 (Fed. Cir. 1991). This is because it is **not obvious** from the disclosure of one species, what other species will work. {M.P.E.P. 2164.03}

Also, as has been ruled by the court in *Genetech Inc. v. Novo Nordisk*, failure to disclose any specific starting material or any condition for preparation constitutes lack of enablement. Thus, relying on the knowledge of one skilled in the art cannot cure such deficiency in enablement (**Genetech Inc. v. Novo Nordisk**, 108 F.3d 1361, 42 USPQ 2d 1001 (Fed. Cir. 1997)).

Note, the “how to use” requirements of 35 USC 112 are not met by disclosing only a pharmacological activity of the claimed compounds if one skilled in the art would not be able to use the compounds effectively without undue experimentation. See **In re Diedrich**, 138 USPQ 128; **In re Gardner et. al.**, 166 USPQ 138. Thus, where the claimed compounds do not bear structures that are similar to known compounds having the same activity, and their pharmaceutical properties could not be predicted from their chemical structure, a disclosure that they possess a particular activity may not suffice as a description of how to use as required by 35 USC 112. See **In re Moureu et. al.** 145 USPQ 452. Note, the Federal Circuit has repeatedly held that “the specification must teach those skilled in the art how to make and use the **full scope** of the invention without ‘undue experimentation’”.

Claim Objections

6. Claims 5, 11 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Search Report

7. The Search Report has been considered because the same references are listed on the IDS of 11-19-01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Tamthom N. Truong
Examiner
Art Unit 1624

May 16, 2002